BEFORE THE

FOOD AND DRUG ADMINISTRATION

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DOCKET NO. 2002N-0278

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PRIOR NOTICE OF IMPORTED FOOD UNDER THE PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT

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COMMENTS OF THE HEALTH & PERSONAL CARE LOGISTICS CONFERENCE, INC.

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I. Introduction

The Health & Personal Care Logistics Conference, Inc. ("H&PCLC") commends the FDA for reopening the comment period in this proceeding to consider public comments on experience gained in complying with the interim final rules that went into effect December 12, 2003. H&PCLC and its members share FDA's interest in harmonizing, to the extent possible, the FDA's Prior Notice of Imported Food program under the Bioterrorism Act of 2002, and the Advance Electronic Presentation of Cargo Information program of Customs and Border Protection under the Trade Act of 2002.

II. Identity and Interest of H&PCLC

H&PCLC is an incorporated non-profit membership association consisting of manufacturers of pharmaceuticals and personal care products. For more than 80 years, H&PCLC has represented the interests of its members in their capacity as shippers and receivers of freight.

Many H&PCLC members are subject to the FD&C Act, and work closely with the FDA in numerous aspects of their operations. While generally not major food producers or importers, members of H&PCLC include companies with animal health operations that are concerned with the Prior Notice of Imported Food program to the extent that it encompasses imported feed and feed ingredients. In addition, H&PCLC members import substances that may be used in foods for human consumption.

III. H&PCLC Supports Many of FDA's Suggested Improvements

It should go without saying that H&PCLC and its members support the goals of enhanced security against bioterrorism that FDA's interim final rule is intended to support. However, it is increasingly clear that efforts to improve the security of the nation's

borders, infrastructure, supply chains, food and feed supplies, etc., may entail costs that affect the nation's economic health.

When Congress established the Department of Homeland Security, it explicitly ordered the new Department, as part of its "primary mission," to "ensure that the overall economy of the United States is not diminished by efforts, activities and programs aimed at securing the homeland." 6 U.S.C. § 111(b)(F).

Concerns about such tradeoffs are particularly acute in today's environment of global competition and just-in-time supply chains. H&PCLC has filed comments with a number of agencies since the terrorist attacks of September 11, 2001, sounding this cautionary note.

H&PCLC appreciates FDA's interest in reducing the burdens of compliance with Section 307 of the Bioterrorism Act, where this can be done consistent with enhanced security. We also commend FDA's decision to focus on education and interaction with affected parties during the first 18 months of the new Prior Notice program.

In reopening the comment period in this Docket, FDA raised several specific questions, and made some specific suggestions aimed at minimizing differences between the FDA and Customs electronic notice programs. H&PCLC supports this goal.

It is clear that FDA is considering shortening the lead times for imports by road, at a minimum. This would mean that prior notice to FDA could be provided no later than 1 hour of arrival at the border, rather than no later than 2 hours, as required by FDA's interim final rule.

If FDA also adopted the Customs time limits for imports by rail and air, there would be similar efficiency gains. For rail imports, the FDA lead time would be reduced

from 4 hours to 2 hours, matching the Customs rule. For air imports, FDA's 4 hour lead time would be shortened to be consistent with the Customs lead time of 2 hours prior to arrival in the U.S., and "wheels up" for flights from nearby origins.

H&PCLC strongly supports these changes for their inherent efficiency gains. The later importers can notify FDA of imports (and receive FDA electronic confirmation of the notice), the more time shippers have to package their food and feed shipments and make sure they meet importers' needs.

In addition, consistency between FDA and Customs, particularly for surface transportation of imports and for imports by air, which tend to be time-sensitive, enables companies to adopt procedures for managing their supply chains that use similar timetables. This should lead to better planning, smoother flows of goods, and improved compliance.

FDA goes on to ask whether special recognition should be given to companies that participate in C-TPAT and FAST. Under Customs' Advance Electronic Cargo Information program, the 1 hour advance notice lead time for truck imports is reduced to ½ hour for FAST shipments. H&PCLC supports a similar arrangement for the FDA. Many H&PCLC members are C-TPAT participants, making their shipments eligible for expedited cross-border processing under the FAST (Free and Secure Trade) program, for which C-TPAT is a prerequisite. C-TPAT certification is only available to companies that have enhanced the security of their supply chains. Shorter lead times for such shipments recognizes the reduced likelihood of contraband. In addition, this change would encourage companies and carriers to become C-TPAT certified, which would improve

security in many ways. H&PCLC does not believe C-TPAT security and verification processes need to be modified first.

FDA asks whether its personnel should conduct inspections of food importers and review their security plans. This should not be required for C-TPAT participants, which must already go through a similar process with Customs. The FDA should seek to reduce duplication of effort where possible. However, H&PCLC supports the suggestion that FDA might offer a training program for brokers and other transmitters and submitters of prior notice of food imports.

With respect to the possibility of phasing in the reduced lead times FDA is considering, as Customs phases in its advance electronic notice regulations, this would promote consistency between the programs. Similar implementation schedules will reduce errors and minimize disruption of supply chains through conflicting requirements.

On the other hand, shorter lead times are also valuable in themselves, and have their own supply chain benefits. Therefore, H&PCLC would not want FDA to delay adopting a reduced timeframe for submitting the required notice merely because Customs is not yet ready to implement the counterpart provisions of its advance notice programs. In addition, the deadlines are minimum periods, and any shipper can provide more notice of imports, to FDA, Customs or both, than the minimums in the regulations. Accordingly, FDA should shorten its lead times to match those in the Customs regulations even if the Customs requirements are not yet in effect.

H&PCLC appreciates the opportunity to submit these comments.

Respectfully submitted,

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